

Health Risk Assessment of Electromagnetic Fields: A Conflict between the Precautionary Principle and Environmental Medicine Methodology

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Abstract: The purpose of the precautionary principle is that legal requirements are to be made to safeguard against the possible health risks that have not yet been scientifically established. That a risk is not established cannot, therefore, be used as an excuse for not applying the principle. Yet, that rationale is exactly what is happening in the case of the possible health risks from exposure to electromagnetic fields (EMF). The scientists, representing both the World Health Organization and the European Commission, do not have at all the precautionary principle in mind when they report on health risks. Their starting point is instead to determine whether new research findings have been scientifically established and thus cannot be the basis for an amendment to the existing exposure limits. Uncertain indications of risk are ignored or played down. This approach is in conflict with European Union (EU) law, which requires that the degree of scientific uncertainty should be presented correctly. A thorough examination of the state of research shows many serious indications of possible health risks from exposure very far below existing limits for EMF. Case law, for other types of exposure, also shows that the precautionary principle can be applied on the basis of weaker evidence than that. Our investigation shows that the precautionary principle is not being used for its intended purpose in relation to exposure to EMF. The reason for this position is that decision-makers are being misled by inaccurate risk assessments.

Keywords: precautionary principle, electromagnetic fields, EMF, risk assessment, risk management

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1. BACKGROUND

Lawyers and scientists make different assumptions when assessing scientific evidence, often leading to communication problems. This disparity includes the formulation of health risk assessments to be used in trials of the precautionary principle. The problem occurs when evaluating the risks for many different types of exposures. Here we will deal with exposure to

electromagnetic fields (EMF), where the problem is clearly visible. Without going into detail on risk assessments, we will compare the authors' own statements on the condition for their reporting with the legal requirements for risk assessment.

Risk assessments are published by the International Commission on Non-Ionizing Radiation Protection (ICNIRP), the World Health Organization (WHO), and the European Commission's Scientific Committee on Emerging

and Newly Identified Health Risks (SCENIHR). This reporting tends to be very similar, which is a consequence of the flow of information from all these bodies being completely controlled by a few experts. For obvious reasons, those people are highly exposed to efforts by industry lobbyists, and their links with industry have often been criticized. We will not address this issue but will instead focus on showing how the reporting differs from the requirements of the precautionary principle. The issue will be discussed from the perspective of European Union (EU) law.

2. CASE LAW CREATED BY THE EU COURT OF JUSTICE

Of course, deciding on measures to protect against scientifically established health risks is possible, but this approach is not an application of the precautionary principle. Scientific uncertainty is a necessary condition for this principle to be invoked. A statement on the meaning of the principle, which the Court often repeats, is expressed as follows in Case C-24/00, paragraph 56:

“It is clear that ... an assessment of the risk could reveal that scientific uncertainty persists as regards the existence or extent of real risks to human health. In such circumstances, it must be accepted that a Member State may, in accordance with the precautionary principle, take protective measures without having to wait until the existence and gravity of those risks are fully demonstrated (see to that effect Case C-157/96 National Farmers' Union and Others (1998) ECR I-2211, paragraph 63). However, the risk assessment cannot be based on purely hypothetical considerations (see Case C-236/01 Monsanto Agricoltura Italia and Others (2003) ECR I-0000, paragraph 106, and Commission v Denmark (C-192/01), paragraph 49).”

A purely hypothetical consideration means that the application has not in any way been preceded by a scientific assessment, as shown in Cases C-236/01 and C-192/01. A scientific risk assessment must, therefore, always be made. There is, however, considerable scope for discretion in the subsequent examination of the applicability of the precautionary principle. In this examination, no high levels of proof are demanded for a risk indicator to justify extensive precautionary measures.

In Case C-157/96 (BSE case), the Commission had decided to suspend all shipments of cattle, beef, and beef products from the United Kingdom to prevent the spread of BSE (mad cow disease). The ban was intended to cover all exports to EU Member States and the rest of the world. The decision was made, inter alia, on the basis of an assessment carried out by a scientific body, which found a very high level of scientific uncertainty. Nevertheless, as a result of theoretical hypothesis, the scientific body reached the conclusion, that the transmission of BSE was the most likely explanation for the emergence of a new variant of Creutzfeldt-Jakob disease that affects humans. In its ruling, the Court concluded that the Commission had applied the precautionary principle in a proper manner when it imposed the export ban.

3. PFIZER CASE

The Court of First Instance (now the General Court) provides in Case T-13/99 (Pfizer case) a good example of how the scientists' approach of rejecting uncertain indications of risk comes into conflict with the precautionary principle.

Pfizer Animal Health SA brought an action for an annulment of Council Regulation 2821/98/EC, in which the Council, relying on the precautionary principle, revoked its previously issued approval of virginiamycin, which Pfizer used as growth promoters in its feed. Virginiamycin is a strepto-

gramin antibiotic. The question was whether the scientific evidence was sufficient to refer to a risk of transmission of resistance to virginiamycin from animals to humans.

The Commission had requested an opinion from its Scientific Committee for Animal Nutrition (SCAN), on which Pfizer relied in support of its claim that the Council had incorrectly applied the precautionary principle. In SCAN's view, no evidence was presented to support the claim that resistance can be transferred in such a manner as to endanger the future use of medicines for human use. The SCAN also stated the conclusion that the use of virginiamycin as a growth promoter did not pose any immediate danger to public health.

The Council relied on two findings to waive the SCAN assessment. In the disputed regulation, recital 19 refers to an observation relating to a farmer and his poultry. Strains of virginiamycin with the same genetic code were found both in the farmer's feces and in feces from one of his turkeys. In this context, the Council stated,

"...even if general conclusions about the transfer of resistant enterococci from animals to humans should not be drawn from a single case, the Commission sees it as an indication that this might be confirmed by other cases in the future."

In recital 20 of the Regulation, the Council refers to an experimental study in rats, which emerged after the SCAN had made its assessment. Following this study, the Commission sought an additional opinion from the SCAN, but their only response was a statement stating that the study did not provide any new information on the subject. In paragraph 297, the Court found that the study had a *"lack of probative value, in SCAN's submission, but some evidential value according to the Community institutions"*.

In paragraph 381, the Court held that SCAN's opinion is based on an incorrect interpretation of the precautionary principle. The Court then

argued that the precautionary principle would no longer serve any purpose if the decision-makers had to wait for evidence of such reliability as CAN had as a basis of its assessment. In paragraph 389 the Court states,

"In the light of the foregoing, the Court finds that the Community institutions did not exceed the bounds of the discretion conferred on them by the Treaty when they took the view that the various experiments and observations referred to in recitals 19 and 20 to the contested regulation were not mere conjecture but amounted to sufficiently reliable and cogent scientific evidence for them to conclude that there was a proper scientific basis for a possible link between the use of virginiamycin as an additive in feeding stuffs and the development of streptogramin resistance in humans."

4. REQUIREMENTS FOR RISK ASSESSMENT

Primarily, case law provides the starting point for the requirements for risk assessment. Additional information is also available from other sources of law. Following the ruling in the BSE case, the Council authorized the Commission to draw up guidelines for use of the precautionary principle. In response to this action, the Commission published a communication on the precautionary principle, COM (2000) 1, in February 2000 /1/. The guidelines have since been adopted by the Council through a resolution /2/.

4.1 Acceptable Level of Risk Should Not Be Determined in the Risk Assessment

The Council resolution, paragraph 11, states that a functional separation should be made between risk assessment and risk management. This condition is explained further in the Commission's communication COM (2000) 1.

The risk assessment is the scientific evaluation of risks carried out by scientists, whereas risk management refers to the political or legal application of the precautionary principle to be performed by decision-makers. Judging what is an 'acceptable' level of risk for society is an eminently political responsibility. Therefore, this issue falls under risk management. The risk assessment is intended to serve only as a basis for that decision.

The Pfizer case, paragraphs 149-163, also confirms this. Paragraph 153 states,

“The level of risk deemed unacceptable will depend on the assessment made by the competent public authority of the particular circumstances of each individual case. In that regard, the authority may take account, inter alia, of the severity of the impact on human health were the risk to occur, including the extent of possible adverse effects, the persistency or reversibility of those effects and the possibility of delayed effects as well as of the more or less concrete perception of the risk based on available scientific knowledge.”

In COM (2000) 1, the Commission also names additional factors to be considered in risk management. Public concern is one such factor. Potential benefits and costs of action, or lack of action, should also be taken into consideration. To provide a comprehensive list that covers all relevant factors is impossible because the assessment must be made on the basis of each individual case. When the precautionary principle is examined by national authorities, often special circumstances must be considered under the applicable national laws. Application of the principle may therefore differ in different Member States.

Risk management therefore involves a global assessment of several factors. For this reason, to specify the level of risk that is acceptable to society in the risk assessment is not possible.

4.2 Degree of Scientific Uncertainty should Be Presented

The Commission's guidelines specify that all efforts should be made to determine the degree of scientific uncertainty as fully as possible in the risk assessment. The reason for this condition is that society's acceptance of the risk should not be determined in the risk assessment.

Case law provides examples of how low the set requirement of scientific evidence can be to lead to the application of the precautionary principle. The case law also provides guidance on how far the scientific risk assessment must be maintained in cases in which the scientific uncertainty is substantial.

According to the BSE case, the investigation should go so far that the most likely explanation for a health problem is determined, even if the scientific support is very weak. The Pfizer case indicates that the findings in a single study may be sufficient proof. An observation that concerns only one individual was also regarded as a sufficient indication of risk, which was invoked in support of an application of the precautionary principle. Such findings must therefore be reported, even if they have not been confirmed in other studies.

The risk assessment may, therefore, not introduce any threshold for how strong the evidence must be before being reported. The degree of scientific uncertainty should be presented correctly, which means that the indications of risk cannot be ignored or belittled.

4.3 Minority Opinions should Be Reported

In situations for which there is scientific uncertainty, sometimes disagreements arise between scientists. These different approaches are useful information for the trials under the precautionary principle. For this reason, paragraph 10 of the Council's resolution states that minority opinions should be reported.

When a scientific committee gives an opinion on a risk, disagreement may arise among members, which means that they are unable to agree on a common conclusion. This minority opinion must then be highlighted in the report. The requirement for the presentation of divergent views, however, should go even further.

In its communication on the precautionary principle (COM (2000), p. 16), the Commission states,

“Even if scientific advice is supported only by a minority fraction of the scientific community, due account should be taken of their views, provided the credibility and reputation of this fraction are recognized.”

The Pfizer case is an example of this condition. The decision to apply the precautionary principle in this case was based on the complex assessments that were the subject of considerable disagreement between scientists. Decision-makers chose to depart from the unanimous conclusion that the scientific committee had reported and instead based its decision on a different scientific assessment of risk. To ensure objectivity and as complete a risk assessment as possible, any disagreements within the scientific community should always be reported.

5. ICNIRP GUIDELINES FOR EMF

The ICNIRP was founded in 1992 and its guidelines, containing the basic restrictions and reference levels for EMF, were published in 1998 /3/. During this initial period, the work was led by Professor Michael Repacholi, who was chairman during the period 1992-1996, and has since served as Chairman Emeritus.

The EU requirements for risk assessment were not specified at the time that ICNIRP guidelines were drafted. Therefore, why ICNIRP has not complied with these EU requirements, at least for the initial period, may be understandable.

In addition, ICNIRP states that the restrictions are based only on established health risks. The guidelines provide, inter alia, that when children are exposed to weak magnetic fields from power lines for a prolonged period, there is a possible risk of leukemia. This risk has not been considered in the exposure limits because the findings were not fully established.

Another relevant factor is that the guidelines are based only on the adverse health effects that can be detected after a few minutes of exposure. This opinion should be seen against the following statement from the Commission:

“It is in situations in which the adverse effects do not emerge until long after exposure that the cause-effect relationships are more difficult to prove scientifically and that—for this reason—the precautionary principle often has to be invoked.” (COM (2000) 1 p. 17).

Furthermore, considering all aspects of the precautionary principle through general exposure limits is not possible. The reason for this is that society's acceptance of risk is determined by reference to the circumstances of each individual case. In addition to exposure level, other factors must be taken into consideration in this risk management.

The limits also include a safety factor. The ICNIRP's intention is to protect against various factors that may make people more sensitive to the established effects. Other potential risks are not considered in any way.

Yet, there are those who argue that the safety factor indirectly provides good protection against risks other than those that have been scientifically established. This view is contradicted by the observation that research has found many serious indications of various health effects from exposure to levels well below the ICNIRP limits.

With regard to public exposure, the safety factor is 50 times. To be misled by this factor is easy, which must be considered in relation to other

factors like the ICNIRP limit for the 3G-frequency being one million billion (10^{15}) times higher than the natural level of exposure to such EMF, to which man has adapted during evolution. In this context, the safety factor is virtually non-existent.

6. APPROACH OF THE WHO

The WHO began its International EMF Project in 1996. Between then and June 2006, the project was led by Professor Repacholi, who therefore had control of both the ICNIRP and WHO. The project resulted in several published papers. Some elements of the Commission's Communication on the precautionary principle (COM (2000) 1) were commented on in a handbook from 2002 /4/, but not the legal requirements for risk assessment design. Instead, the authors were of the view that the precautionary principle does not apply when setting requirements for exposure below the ICNIRP limits. The authors also warn authorities against using the precautionary principle at the lower levels of exposure, claiming it undermines the credibility of science and exposure limits!

In 2006, the WHO also published a model legislation, the aim of which is to assist countries in implementing the ICNIRP guidelines as law /5/. The legislation states that no precautionary measures may be taken that undermine the exposure limits! EU Member States have not used this model legislation, but unfortunately the idea that the precautionary principle cannot be applied below the ICNIRP limits received strong support.

As we have mentioned earlier, the precautionary principle is defined in such a way that it assumes the existence of scientific uncertainty, which leads to a logical conclusion. That a risk is not yet fully established scientifically cannot serve as an excuse for not applying the principle. The information of the WHO is thus incorrect. Because the ICNIRP limits are based only on established risks, the precautionary principle has its scope at lower levels.

In another publication from 2006, the WHO stated that they are working on producing a guide for decision-makers on how the precautionary principle should be applied /6/. The aim is to develop various proposals for measures to protect public health, which the WHO has already taken into account:

"...the degree of scientific uncertainty and the anticipated severity of the harm that might ensue, taking into account the size of the affected population and the cost".

This should be done in such a way as not to undermine the basis for the scientific risk assessment and scientifically based exposure limits.

Although such guidance has not yet been presented, this statement does, however, raise questions. How can this goal be achieved without undermining the role of decision-makers to undertake a comprehensive assessment of all the relevant circumstances of each individual case? Does the WHO intend to comply with the EU requirement that risk assessment and management should be distinguished between? We should also note that EU law requires that both risk assessment and risk management should be transparent (see for example, Council resolution, paragraph 14).

The EU requirements on risk assessment do not change the criteria used to assess the strength of scientific evidence, such as the Bradford Hill criteria. The degree of scientific uncertainty, however, must be presented in a correct manner, which requires a fundamental change in the position of the WHO, but does not undermine the basis of the scientific risk assessment.

7. RISK ASSESSMENTS OF SCENIHR

The Commission's scientific committee, SCENIHR, has also appointed a working group to evaluate the health risk associated with EMF. Initially, the group was led by Professor Anders Ahlbom, who was for many years also a leading

figure in ICNIRP and actively involved in the work of the WHO. Along with Professor Repacholi, Professor Ahlbom is therefore one of those who coordinates the approach of these agencies to the risk assessment issue.

In the autumn of 2006, the working group presented a preliminary report. The work was then subjected to a public consultation, resulting in extensive criticism. Various researchers provided information on how important discoveries in their areas had been ignored or played down. They also pointed out that the working group had not followed the guidelines for the precautionary principle.

The criticism did not result in changes to any conclusions, but the working group appears to at least have been given the task of explaining the method they used in the evaluation. The final report, which was presented in 2007, included a new section on methodological issues /7/. This section, however, describes only the criteria for assessing the strength of the scientific proof. The requirements of EU law are not considered at all. A debate in a Swedish journal also indicates that Professor Ahlbom did not consider that the precautionary principle imposes any requirements on risk assessment /8,9/.

Some of the scientists who had previously expressed their views on SCENIHR's preliminary report published their own report in the Autumn of 2007 (BioInitiative Report) /10/. The report gives a very detailed picture of the risk indications that SCENIHR has ignored or belittled. SCENIHR published a new report in 2009 /11/. This report, however, did not address the disagreement within the scientific community as expressed in the BioInitiative Report, even though SCENIHR was well aware of these views. The reporting is also of such a nature that the precautionary principle cannot be used for its purpose, namely, to allow legal requirements for measures to protect against possible risks. The problem can be illustrated by an example.

The BioInitiative Report states that more than a dozen scientific studies have been done on how mobile phone usage affects the risk of cancer in users. The authors have carried out a total appraisal of these studies that indicate an increased risk of both brain tumors and auditory nerve tumors (acoustic neuromas). The conclusion is,

“For brain tumors, people who have used a cell phone for 10 years or longer have a 20% increase in risk (when the cell phone is used on both sides of the head). For people who have used a cell phone for 10 years or longer predominantly on one side of the head, there is a 200% increased risk of a brain tumor.”

The risk is said to be even greater for auditory nerve tumors.

In both reports, SCENIHR has spoken out in the same way on this issue, with this conclusion:

“The balance of epidemiologic evidence indicates that mobile phone use of less than 10 years does not pose any increased risk of brain tumor or acoustic neuroma. For longer use, data are sparse and conclusions therefore are uncertain. From the available data, however, it does appear that there is no increased risk for brain tumors in longterm users, with the exception of acoustic neuroma for which there are some indications of an association.”

The dispute lies in the different assessments of existing studies. SCENIHR has set a very high certainty requirement for its assessments and therefore filters out risks that are not yet established. The risk of brain tumors with more than 10 years' use of mobile phones is ignored, and the risk of acoustic neuroma belittled. This conclusion means that the degree of scientific uncertainty is not correctly reflected, with the result that the precautionary principle cannot be used for its intended purpose.

The scientists who formulate risk assessments for SCENIHR have exactly the same attitude as the ICNIRP and WHO. The starting point for their risk assessment is to determine whether new research has emerged, which means that existing exposure limits should be adjusted. Indications of risk that are not yet fully established are, therefore, dismissed. Decision-makers are misled by this, which must be perceived as particularly serious.

The EU has adopted the ICNIRP basic restrictions and reference levels in Council Recommendation 1999/519/EC. The EU stated that the recommendation is based only on scientifically established risk, but the Council's intention was to retrospectively incorporate aspects of precaution. The Commission is requested to,

“Keep the matters covered by this recommendation under review, with a view to its revision and updating, taking into account also possible effects, which are currently the object of research, including relevant aspects of precaution...”

Despite this request, the Commission has never proposed any amendment to the recommendation. The reason is stated in its report, COM (2008) 532, p. 10:

“In 2007, the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) reviewed the scientific knowledge on potential health effects of EMF and found no consistent scientific evidence showing a need for revising the basic restrictions and reference levels set out in the Council Recommendation.”/12/

SCENIHR's misleading risk assessment therefore means that the Commission is guilty of the fundamental mistake of wrongly rejecting the precautionary principle on the grounds that the risks are not yet fully established scientifically!

8. CONCLUSIONS

We conclude that both WHO and SCENIHR are designing their risk assessments in such a way that the precautionary principle cannot be used for its intended purpose. The work of the WHO is not controlled by the EU. The WHO often disclaims any responsibility for information in the reports. We therefore advise against uncritical use of its risk assessments. In many cases, the information in its reports and fact sheets is wrong, because the data are based on a misunderstanding of the precautionary principle.

By ruling in the Pfizer case, the Commission has been criticized for their scientific committee had misunderstood the precautionary principle and based its statement on false assumptions. SCENIHR's reports on the health risks of EMF show that this problem persists and occurs more generally.

The Commission has announced internal instructions for its scientific committees, but these are inadequate. The appointed scientists have misinterpreted their mandate and seem to believe that it is up to them to determine what level of risk is acceptable to society. Because this viewpoint is concealed by the incorrect reflection of the degree of scientific uncertainty, the problem is very difficult for the decision-makers who are responsible for risk management to detect.

Knowledge of how risk management works is required for a risk assessment to be correct. We therefore propose that the working groups be supplemented with legal expertise. They must also be provided with substantially clearer instructions on the conditions of their mission.

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